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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,715	01/09/2002	Jeanette McCarthy	VTY2002-01R	6424

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MILLENNIUM PHARMACEUTICALS, INC.
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EXAMINER	
MORAN, MARJORIE A	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/043,715	MCCARTHY, JEANETTE	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2002*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-130* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-130* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-30 and 50-57, drawn to methods to identify a subject as a candidate for a particular course of therapy or further diagnostic evaluation for a vascular disease and to select a course of therapy by determining the identity of specific nucleotides of SEQ ID NO: 1, classified in class 435, subclass 6. This Group is further subject to an election of species, as set forth below.

II. Claims 31-40, drawn to a computer readable medium, processor, system and method for determining whether a subject is predisposed to a vascular disease based on polymorphism of an EDN1 gene, classified in class 702, subclass 19.

III. Claims 41-44, drawn to a method of diagnosing a vascular disease by identifying an EDN1 genetic profile, classified in class 435, subclass 6. This Group is further subject to an election of species, as set forth below.

IV. Claims 45-47, drawn to a method for selecting an appropriate drug, classified in class 702, subclass 20.

V. Claims 48-49, drawn to a method for treating a disease or disorder associated with allelic variants of an EDN1 gene, classified in class 514, subclass 1.

VI. Claims 58-61, drawn to an isolated nucleic acid and kits comprising probes or primers, classified in class 536, subclass 23.1.

VII. Claims 62-72, drawn to a method of identifying allelic variants of a gene, classified in class 435, subclass 6. This Group is further subject to an election of species, as set forth below.

VIII. Claims 73-87, drawn to methods and devices for assessing a subject's risk of vascular disease, classified in class 702, subclass 19.

IX. Claims 88-98, drawn to methods of self-assessing health, classified in class 702, subclass 19.

X. Claims 99-130, drawn to methods of providing medical assessments and advice, classified in class 705, subclass 2. This Group is further subject to an election of species, as set forth below.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-V and VII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods reciting different steps, are directed to different results, and recite use of different products. In addition, the method(s) of any one Group may be preformed without knowledge of or reference to the steps or results of the method(s) of any other Group.

Invention VI is not related to any of Inventions I-V and VII-X. None of the methods of Groups I-V and VII-X recites use or production of the product of Group VI,

and the product of Group VI is not limited to be one for use in or to be made by any of the methods of Groups I-V or VII-X.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for any one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

If Group I is elected, applicant must elect from the following patentably distinct species of the claimed invention:

A course of therapy which includes (A) use of a medical device; (B) a surgical procedure or (C) vascular imaging.

For any claims which encompass use of a medical device (i.e. species (A) above), applicant must elect a single medical device; e.g. from those listed in claim 5. For any claims which encompass a surgical procedure, (i.e. species (B) above), applicant must further elect a single procedure; e.g. from those listed in claim 7.

If Group III is elected, or if species (C) of Group I is elected, or any other claims which encompass vascular imaging are elected, applicant is required to elect a single vascular imaging device; e.g. from those listed in claims 11 and 44.

Currently , claims 1-2, 8-9, 12-14, and 50-53 are generic for Group I, and claims 40-42 are generic for Group III.

If Group VII is elected, applicant is required to elect a single species of determining the identity of an allelic variant; e.g. from among those listed in claims 64-65 and 67-71. Currently, claims 62-63, 66, and 72 are generic.

If Group X is elected, then applicant is required to elect molecular data and a profile comprising nucleic acid data and a genetic profile (claim 112) OR comprising protein sequence data and a proteomic profile (claim 113) OR comprising information regarding the various compounds recited in claim 114.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363 until January 12, 2004. After that date, the telephone number will be (571)272-0720. The examiner can normally be reached on Monday to Wednesday, 7:30 am to 4 pm EST, Thursday, 7:30 am to 6 pm EST, and Friday, 7 am to 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

Marjorie A. Moran

MARJORIE MORAN
PATENT EXAMINER

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